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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,121	05/02/2001	Richard Rosenbloom	QUIG-1002US	5413

7590 01/02/2002

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EXAMINER	
BAHAR, MOJDEH	
ART UNIT	PAPER NUMBER
1617	5

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/847,121	Applicant(s) ROSENBLOOM, RICHARD	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7-9,11,14 and 16-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10,12,13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to the first office action of July 18, 2001, submitted October 18, 2001 (Paper No. 4) is acknowledged.

Applicant's remarks and amendments submitted October 12, 2001 in Paper No. 4 are persuasive to remove the claim objections and rejection under 35 USC 112 as to lack of antecedent basis in claim1 and the rejection under 35 USC 102 in the previous office action.

Applicant's confirmation of the election with traverse of Group I, claims 1-15 in Paper No. 4 submitted October 12, 2001 is acknowledged. Applicant's traversal on the ground that the examiner's position that the process as claimed can be practiced with another materially different product is incorrect. Applicant's argument in this regard has been considered but is not found persuasive. The process as claimed is "a method of treating diabetic neuropathy". "A method of treating diabetic neuropathy" can be practiced with a materially different product, e.g., an anti-diabetic agent and a prostaglandin I derivative.

As shown in the restriction requirement of July 18, 2001 the different species of aldose reductase inhibitors and antioxidants are classified in many different subclasses. To illustrate this diversity, consider the following examples of aldose reductase inhibitors: indole is classified in class 514, subclass 415, trifolin is classified in class 514, subclass 461; juglanin, apiin, rutin are classified in class 514, subclass 456, for example. To illustrate this diversity, consider the following examples of antioxidents: Vitamin E is classified in class 514, subclass 458; ascorbic acid is classified in class 514, subclass 474; lipoic acid is classified in class 514, subclass 440; rutin and fisetin are classified in class 514, subclass 456; for example. Furthermore, the search

for all species and combinations thereof is therefore an undue burden on the office. Note that the search is not limited to patent files.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-25 and 7-9, 11, 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions and species respectively, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 4.

This application contains claims 16-25 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-6, 10, 12-13 and 15 are herein examined on the merits in so far as they read on the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to

consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "Vitamin D3", does not reasonably provide enablement for "other vitamin D3 derivatives which promote the synthesis of nerve growth ". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant fails to set forth the criteria that defines neither a "other vitamin D3 derivatives which promote the synthesis of nerve growth ". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, the applicant defines the term "derivative" to mean "compounds which possess at least one structural moiety in common with the compound from which they are derived." This definition can give rise to many possible variations since the additional moieties can have varying structures. Furthermore the activity of compounds based

on their structural diversity is unpredictable. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "other vitamin D3 derivatives which promote the synthesis of nerve growth" necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Applicants' arguments and references submitted October 18, 2001 have been considered but are not persuasive to remove the rejection under 35 USC 112, 1st paragraph. Note that under applicant's definition of a "derivative" any organic compound having a benzene ring any where in its structure is a benzene "derivative", even if the benzene is a substituent free of any physiological activity. Such broad definition of the term "derivative" is not enabled by the specification as discussed herein above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "topical composition as claimed in claim 1" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 1-6, 10, 12-13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1-6, 10, 12-13 and 15 recite the broad recitation "other vitamin D3 derivatives which promote the syntheses of NGF", and the claim also recites "vitamin D3" or "a vitamin D3 derivative" which is the narrower statement of the range/limitation.

Applicant's argument that Vitamin D3 is not a Vitamin D3 derivative has been considered but is not persuasive to overcome the instant rejection because according to the applicant's own definition, a "derivative" encompasses "compounds which possess at least one structural moiety in common with the compound from which they are derived." Vitamin D3 and Vitamin D3 derivatives as well therefore meet applicant's definition of a derivative. Please also note that the claims recite the employment of vitamin D3 per se, as a nerve growth factor synthesis promoter, see e.g., claim 2 herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 10, 12-13 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (USPN 5,976,568), of record in the previous office action .

Riley (US 5,976,568) discloses an oral daily supplement composition comprising Vitamins A, D, E, C (Buffered Calcium Ascorbate, Ascorbic Acid and Ascorbyl Palmitate) and quercetin, see claim 2. Riley (US 5,976,568) also discloses an oral daily supplement composition comprising vitamins A, C, D3 and E, see claim 3. See alsoTable II columns 25 and 28.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an amount affective to promote nerve growth of a vitamin D3 derivative, ascorbyl palmitate and quercetin in a single topical composition.

One of ordinary skill in the art would have been motivated to incorporate the Riley composition in a topical composition sine interconversion of dosage forms is within the skill of the artisan.

Note that applicant's amendment submitted October 18, 2001, added the new limitation "topical" in claim 2 and changed claim 1 to read "composition" instead of "compositions", thereby necessitating a change in the rejection under 35 USC 102 in the previous office action to the instant obviousness rejection in the present action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
December 21, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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